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OFFICE OF PETITIONS

In re Patent No. 7,459,541

Hall et al.

Issue Date: 12/02/2008 :

Application No. 10/733852 Filing or 371(c) Date: 12/10/2003

Attorney Docket No. 14230-010002

DECISION ON APPLICATION FOR

PATENT TERM ADJUSTMENT

· UNDER 37 CFR 1.705(d)

This is a decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)," filed January 29, 2009. Patentees assert that the adjustment of 61 days accorded in connection with the reply to the Notice to File Missing Parts of Nonprovisional Application is incorrect, and that the correct adjustment in this regard is 66 days. Patentees further argue that application is entitled to an additional adjustment of 723 days in accordance with 37 CFR 1.703(b).

The application for patent term adjustment is granted to the extent indicated herein.

The above-identified application matured into U.S. Patent No. 7,459,541 on December 2, 2008. The patent issued with a patent term adjustment of 612 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See, 37 CFR 1.705(d). Patentees request that the patent term adjustment determination for the above-identified patent be changed from 612 days to 907 days.

Patentees request recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), of 723 days and the period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), of 300 days do not overlap as these periods do not occur on the same day.

The 723-day period is calculated based on the application having been filed under 35 U.S.C. 111(a) on December 10, 2003, and the patent having been issued on December 2, 2008, three years and 723 days later. Patentees assert that in addition to this 723-day period, they are

entitled to a period of adjustment due to examination delay pursuant to 37 CFR 1.702(a) totalling 300 days. This 300-day period is the period of delay for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date on which application was filed under 35 U.S.C. 111(a), pursuant to 37 CFR 1.702(a)(1). A non-final Office action was mailed on December 7, 2005, 14 months and 300 days after the application was filed on December 10, 2003.

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, patentees are entitled to the period of Office delay reduced by the period of applicant delay.

Patentees note that the Office incorrectly calculated the period of reduction of 61 days attributed to Applicant pursuant to 37 CFR 1.704(b), for filing a reply to the Notice to File Missing Parts of Nonprovisional Application, mailed May 20, 2004. The Office incorrectly noted October 20, 2004 as the date that the reply was filed; however, as indicated by patentees, the reply was filed on October 25, 2004, three months and 66 days after the Notice was mailed. Patentees do not dispute the reductions of 31 days and 19 days for applicant delay.

Patentees do not dispute that the total period of Office delay is the sum of the period of Three Years Delay (723 days) and the period of Examination Delay (300 days) to the extent that these periods of delay are not overlapping. However, in effect, patentees contend that no portion of the Three Year Delay period overlaps with the period of examination delay. Accordingly, patentees submit that the total period of adjustment for Office delay is 1023 days, which is the sum of the period of Three Year Delay (723 days) and the period of Examination Delay (300 days), reduced by the period of overlap (0 days). As such, patentees assert entitlement to a patent term adjustment of 907 days (723 days + 300 days reduced by 0 days overlap – 116 days (66 days + 31 days + 19 days applicant delay)).

The Office agrees that as of the issuance of the patent on December 2, 2008, the application was pending three years and 723 days after its filing date. The Office agrees that certain action was not taken within the specified time frame, and thus, the entry of a period of adjustment of 300 days is correct. At issue is whether patentees should accrue 723 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 300 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 300 days overlap. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718<sup>1</sup>

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, December 10, 2003, to the date the patent issued on December 2, 2008. Prior to the issuance of the patent, 300 days of patent term adjustment were accorded for the Office failing to respond within a specified time frame during the pendency of the application. All of the 300 days for Office examination delay overlap with the 723 days of Office delay in issuing the patent. During that time, the issuance of the patent was delayed by 723 days, not 723 days + 300 days. The Office took 14 months and 300 days to issue a first Office action. Otherwise, the Office took all actions set forth in 37 CFR 1.702(a) within the prescribed timeframes. Nonetheless, given the initial 300 days of Office delay and the 116 days of applicant delay and the time allowed within the time frames for processing and examination, the application issued three years and 723 days after its filing date. The Office did not delay 723 days and then an additional 300 days. Accordingly, 723 days of patent term adjustment (not 723 days and 300 days) was properly entered because the 300 days attributable to examination delay overlaps with the adjustment of 723 days attributable to delay in issuance of the patent. Entry of both periods is not warranted.

<sup>&</sup>lt;sup>1</sup> The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106<sup>th</sup> Cong. 1<sup>st</sup> Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

Accordingly, the patent will be accorded an overall adjustment of 607 days (adjustments totalling 723 days less reductions totalling 116 days).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

The application file is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify the Office error pursuant to 37 CFR 1.704(b) as noted *supra*. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by **six hundred seven (607)** days.

Any request for reconsideration of this decision must be submitted within ONE MONTH of the mail date indicated herein. The time period for seeking reconsideration is not subject to extension under 37 CFR 1.136.

Telephone inquiries specific to this matter should be directed to Attorney Derek Woods, at (571) 272-3232.

Alesia Brown

Senior Petitions Attorney

Office of Petitions

Office of the Deputy Commissioner

for Patent Examination Policy

Enclosure: Copy of DRAFT Certificate of Correction

## UNITED STATES PATENT AND TRADEMARK OFFICE **CERTIFICATE OF CORRECTION**

PATENT

: 7,459,541 B2

DATED

: December 2, 2008

INVENTOR(S): Hall et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

Subject to any disclaimer, the term of this patent is extended or adjusted [\*] Notice: under 35 USC 154(b) by (612) days.

Delete the phrase "by 612 days" and insert - by 607 days--